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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,869	12/11/2001	Kevin P. Baker	GNE.2830P1C45	9681

35489 7590 06/03/2005

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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/015,869

Applicant(s)

BAKER ET AL.

Examiner

Fozia M. Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,38-40 and 44-54 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 33,38-40 and 44-47 is/are allowed able
6) ☐ Claim(s) 48-54 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1a. Receipt of Applicants' amendment and arguments, filed on 14 March 2005 is acknowledged. Claim 33 and 48 are currently amended.

Status of Claims:

1b. Claims 1-32, 34-37 and 41-43 have been cancelled. Claims 33, 38-40 and 44-54 are pending and under consideration.

Information Disclosure Statement:

2a. The information disclosure statements filed 13 November 2002 and 17 September 2002, fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because they fail to identify each reference by author and publication date. The references have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

3. ***Priority:***

Applicants note that the effective filing date of the present application is 29 October 1999, the filing date of U.S. Provisional Patent Application Serial Number 60/162,506.

Applicants are correct in that claims 33, 38-40 and 44-47 are afforded the benefit of the filing date of the U.S. Provisional Application No. 60/162,506, which was filed October 29, 1999. However, claims 48-54 which are drawn to fragments of the nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:76 that hybridize the nucleic acid of SEQ ID NO:76, or complement thereof, do not get the benefit of the effective filing date of 29 October 1999, the filing date of the U.S. Provisional Application No. 60/162,506, because the parent application does not disclose that fragments of the nucleic acid of SEQ ID NO:76 are amplified in lung or colon tumors. Thus, claims 48-54 are afforded an effective filing date of 12/11/2001, which is the filing date of the current application.

4. The following previous objections and rejections are withdrawn in light of Applicants amendment filed 03/14/05.

(I) All of the rejections made against cancelled claims 34-37 are moot.

(II) The rejection of claims 33, 44-47 made under 35 U.S.C. 112, first paragraph, for not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, is withdrawn. Claims 33 and 44-47 are now drawn to an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:76, and a vector comprising said nucleic acid and a host cell comprising said vector. Therefore, the invention recited in claims 33 and 44-47 is now enabled, because the instant specification demonstrates that nucleic acid of SEQ ID NO:76 is amplified in lung or colon tumors. Thus, one of ordinary skill in the art would know how to make and use said nucleic acid.

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(III) The rejection of claims 46-47, made under 35 U.S.C. 101, for encompassing a product of nature, is withdrawn, because claim 46 now recites "an isolated host cell...".

(IV) The objection of claims 38-40, for depending on a rejected base claim is withdrawn, because now claim 33, from which these claim depend is now allowable.

Response to Applicants' arguments:

5a. Claims 48-54 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record, set forth in the office action mailed on 12/14/2004, pages 4-5.

Applicants argue that instant claim 48 has been amended to recite a fragment of the nucleic acid of SEQ ID NO:76, or complement thereof, therefore, the instant specification is enabling for said fragment, since it is enabling for the nucleic acid of SEQ ID NO:76. Applicants conclude that the instant specification detail how to make and use the claimed nucleic acid for the diagnosis of lung and colon cancer, by using diagnostic methods based on hybridization to such amplified sequences.

These arguments have been fully considered and are deemed persuasive in part. The instant specification as well as the parent application discloses that the full length sequence of SEQ ID NO:76 is amplified in lung and colon tumors compared to normal controls. Therefore, a fragment of the nucleic acid of SEQ ID NO:76 that consists of 20 to 100 nucleotides would be useful as a probe. However, fragments that hybridize to the nucleic acid of SEQ ID NO:76, would not be useful as probes, because primers that are not identical to the desired nucleic acid cannot be used as probes. Therefore, the instant specification is enabling for an isolated nucleic acid that consists of 20-100 nucleotides of SEQ ID NO:76, but does not enable for a fragment that consists of 20-

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100 nucleotides that hybridizes to SEQ ID NO:76, because non-identical primers are not useful as probes. Although fragments that hybridize to the nucleic acid of SEQ ID NO:76 can be made by one skilled in the art, the skilled artisan would not know how to use them.

Claim Rejections - 35 U.S.C. §102:

6a. Claims 48-54 (are afforded an effective filing date of 12/11/2001) stand rejected under U.S.C. § 102 (a) as being anticipated by Baker et al (WO200012708; published on 09 March 2000), or Robert Strausberg (10/20/2000) or Ansorge et al (02/18/2000), for reasons of record et forth in the office action mailed on 14 December 2004, pages 7-8.

Applicants submit that claim 48 is now drawn to an isolated nucleic acid molecule consisting of at least 20 nucleotide fragment of the nucleic acid of sequence of SEQ ID NO:76 or a complement thereof that specifically hybridizes, as such claim 48 is not drawn to a variant of SEQ ID NO:76, but claims a fragment of SEQ ID NO:76 or a complement thereof.

This argument is not found persuasive, because each of the references discloses an isolated nucleic acid molecule that comprises more than 100 contiguous nucleotides of the nucleic acid of SEQ ID NO:76.

Instant claims 48-54 are drawn to an isolated nucleic acid molecule consisting of an at least 20 to 100 nucleotides in length of D SEQ ID NO:76 or a complement thereof, that specifically hybridizes under stringent conditions to the nucleic acid of SEQ ID NO:76 or a complement thereof. Therefore, since each of the references discloses an

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isolated nucleic acid that comprises at least 100 nucleotides of SEQ ID NO:76, complement of the nucleic acid of the references would also be expected to hybridize to the nucleic acid of SEQ ID NO:76, Thus, all of the references anticipate claims 48-54.

Conclusion:

8. Claims 33, 38-40 and 44-47 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud

Patent Examiner

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25 May 2005


JANET ANDRES
PRIMARY EXAMINER